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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,715	05/14/2007	Sergey I. Chernysh	SPSUP0100WOUS	4071
23908 7590 10/13/2009 RENNER OTTO BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE NINETEENTH FLOOR CLEVELAND, OH 44115			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 10/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,715	Applicant(s) CHERNYSH ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/06, 12/17/08, 3/4/09</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-17 and 21-26, a peptide comprising SEQ ID No. 1, in the reply filed on December 17, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 17, 2008.

3. Claims 1-17 and 21-26 are under examination. The sequences of SEQ ID Nos. 13 and 18 are encompassed by the sequence of SEQ ID No. 1 and are therefore under examination with SEQ ID No. 1.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on October 30, 2006, December 17, 2008, and March 4, 2009 have been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

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5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

6. The disclosure is objected to because of the following informalities: the specification contains sequences on page 4 which are not identified by SEQ ID No. and do not appear to be included in the sequence listing. See 37 CFR §1.821-1.825.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-13, and 21-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-13 and 21-25, as written, do not sufficiently distinguish over peptides as they exist naturally because the claims do not particularly point out any non-naturally

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occurring differences between the claimed peptides and the structure of naturally occurring peptides.

In the absence of the hand of man, the naturally occurring peptides are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" peptide or similar language would obviate this rejection.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 6-17, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishleigh, et al. (US PAT 5773572, issued June 30, 1998, as cited on the PTO-892 mailed November 21, 2008).

The claims recite a peptide comprising a compound having the general structural formula: X1 Trp Gly Gln X2 or pharmaceutically acceptable salts, or ethers, or amides thereof, wherein X1 is absent or comprises no less than 1 amino acid, and X2 is absent

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or comprises no less than 1 amino acid, comprising up to 30 amino acid residues, having antiproliferative and cytotoxic activity, having antitumoral activity, having antiviral activity, having immunomodulating activity. A protein comprising the amino acid sequences of claim 1, having antitumoral activity, having antiviral activity, having immunomodulatory activity. A chemical compound having anti-proliferative, cytotoxic, antitumoral or antiviral activity, comprising the amino acid sequence as defined in claim 1, wherein the chemical compound is not a natural peptide or protein. A pharmaceutical composition comprising the peptide of claim 1. A pharmaceutical composition comprising the protein of claim 6. A pharmaceutical composition comprising the chemical compounds of claim 14. A polypeptide comprising the amino acid sequence of claim 1, having antitumoral activity, having antiviral activity, having immunomodulatory activity. A pharmaceutical composition comprising the polypeptide of claim 22.

Fishleigh, et al. teach polypeptides of SEQ ID Nos. 30, 31, and 46 each of which comprise the formula $X_1 \text{ Trp Gly Gln } X_2$. SEQ ID No. 30 consists of 16 amino acids. SEQ ID No. 31 consists of 29 amino acids. SEQ ID No. 46 consists of 26 amino acids. The polypeptides relate to human prion proteins and are thus part of a protein as required by claim 6. The antiproliferative, antitumoral, antiviral, and immunomodulatory activities are inherent properties of the polypeptide sequence and as such, the sequences of Fishleigh, et al. would have antiproliferative, antitumoral, antiviral, and immunomodulatory activities. Fishleigh, et al. teach the sequences in synthetic polypeptides comprising D-amino acids (see claims) which meets the limitations of

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claim 14 that the polypeptide not be natural. Fishleigh, et al. teach the polypeptides in a pharmaceutical composition. Since the claims do not define the specific sequence of the complete polypeptide, and Fishleigh, et al. teach polypeptides comprising the Trp Gly Gln core sequence, all the limitations of the claims have been met.

Conclusion

11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Frangione, et al. (US PG PUB 2003/0166558, published September 4, 2003).

Frangione, et al. teach polypeptide sequences which are immunogenic and contain the sequence Trp-Gly-Gln.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
October 7, 2009

/Anne M Gussow/
Examiner, Art Unit 1643